REMARKS/ARGUMENTS

Claims 1-3 and 6-10 remain pending in the instant application. Favorable reconsideration is kindly requested.

Rejection under 35 U.S.C. § 103

Claims 1-3 and 6-11 are rejected under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,254,097 to Schock, *et al.* ("Schock"), taken alone. Applicant respectfully traverses the rejection.

Independent claim 1 recites a device for injection, comprising, *inter alia*, "a second connecting component (6) having a second port (7), that is sealed by a first flexible air- and liquid-proof membrane (17)... said first flexible air- and liquid-proof membrane (17) sealing said second port (7) cooperates with a second flexible membrane arranged in an injection component (11) which is connectable to said second connecting component (6), and the device has a means (18) for holding said second flexible membrane with a pressure against said first flexible air- and liquid-proof membrane (17)" (markup per 37 C.F.R. § 1.121). Applicant's previous response pointed out that Schock does not teach or suggest these features, notwithstanding the proposed amendments.

In the "Response to Arguments" section (p. 3) the Office Action suggests that the catheter tubing is considered a flexible membrane. Applicant respectfully disagrees. An ordinarily skilled person in the art would not make such a characterization. It is well established that claims are not to be read in a vacuum. *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir., 1983). Moreover, claim terms are to be interpreted "not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction **in light of the specification as it would be interpreted by one of ordinary skill in the art.**" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*) (emphasis added). In this case, one of ordinary skill in the art would not interpret "membrane" in the manner asserted by the Office Action. The structure of Schock is properly described as a tubing or sheath, and would be mischaracterized if described as a membrane.

More particularly, in contrast to present claim 1, Schock discloses a channel (secondary lumen 42) provided with a (hemostatic) valve at its distal end. The valve includes a puncture or slit portion 46 (per Col. 5, lines 29-39; Figs. 2, 4, 5 and 7). Such a device could not be used to

ensure a high degree of imperviousness against leakage when supplying medical substances to the device by an injection component having a flexible membrane. This is in part because applying pressure to the slit portion 46 would cause it to open, and the contents of the device could therefore leak out.

A device according to claim 1 enables the safe transfer of a substance from the injection component into the device without contamination of the fluids inside the device, or leakage of medical substances from the device into the ambient air. First and second membranes are pressed together, and are penetrated by an injection device through the membranes, and maintain their sealing properties when the injection device is withdrawn through the membranes.

Accordingly, without admitting that this purported equivalence set forth in the Office Action is valid, even considering the catheter tubing as a "flexible air- and liquid-proof membrane" does not reach the language of claim 1. Specifically, claim 1 is amended to recite "the injection component penetrating the first and second flexible membranes". This amendment is fully supported by the specification, for example at p. 5, among other places, and no new matter has been added. Because the Office Action considers the catheter tubing of Schock's injection device as a second membrane, the element characterized as an injection device, guide wire 58, does not penetrate the so-called second membrane, but rather passes through the tubing without penetration.

Finally, Applicant respectfully traverses the proposed modification of Schock to alter the first channel as extending in a generally straight line through the device, which the Office Action admits it does not. The Office Action avers that the device would function equally well in either arrangement as alleged motivation for the modification. Applicant respectfully submits that this acknowledgement is the precise reason that one of ordinary skill in the art would not so modify Schock, because there is no apparent advantage to be gained in view of Schock's teachings. Moreover, Schock teaches that the second port is for the introduction of a guide wire for catheterized surgical tools and techniques. Modifying the device of Schock to make the first channel straight would force a bend in the second guide wire channel. This additional bend is more preferably avoided by maintaining the orientation Schock discloses. A prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983).

Therefore, Applicant respectfully submits that the rejection of claim 1 has been obviated, and kindly requests favorable reconsideration and withdrawal. Claims 2-3 and 7-10 each depend, either directly or indirectly, from independent claim 1, and incorporate its features by reference. These dependent claims are each separately patentable, but in the interest of brevity, they are offered as patentable for at least the same reasons as their underlying independent base claim. All claims are therefore submitted as patentable over Schock, and favorable reconsideration and withdrawal of the rejection is kindly requested.

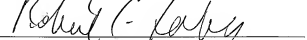
Conclusion

In light of the foregoing, Applicant respectfully submits that all claims are patentable, and kindly solicits an early and favorable Notice of Allowability.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON December 9, 2008.

RCF:DJT/jl

Respectfully submitted,



Robert C. Faber
Registration No.: 24,322
OSTROLENK, FABER, GERB & SOFFEN, LLP
1180 Avenue of the Americas
New York, New York 10036-8403
Telephone: (212) 382-0700